PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
2002039-WO		
International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/DK 03/00853	11.12.2003	11.12.2002

International Patent Classification (IPC) or both national classification and IPC

A61M25/00

Applicant

COLOPLAST A/S ET AL.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
24.05.2004	10.05.2005

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK 03/00853

I. **Basis of the report**

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-18 as originally filed

Claims, Numbers

1-29 filed with telefax on 11.02.2005

Drawings, Sheets

1/2-2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 22,24-26

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 22,24-26

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-20,28,29
	No:	Claims	21,23,27
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-21,23,27-29
Industrial applicability (IA)	Yes:	Claims	1-21,23,27-29
	No:	Claims	

2. Citations and explanations

see separate sheet

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Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: WO 91/00074 A (NILSSON LEIF) 10 January 1991 (1991-01-10)
D2: US-A-6 048 332 (DUFFY NIALL ET AL) 11 April 2000 (2000-04-11)
D3: WO 02/24246 A (HUNTER GARY FRANCIS) 28 March 2002 (2002-03-28)
D4: US-A-4 603 152 (LAURIN DEAN ET AL) 29 July 1986 (1986-07-29)
D5: US-A-6 053 905 (WALLS JAMES A ET AL) 25 April 2000 (2000-04-25)
D6: US-A-6 050 934 (JOHNSON SHELLEY N ET AL) 18 April 2000 (2000-04-18)

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1 and discloses (see page 8, line 3-19 and figures, the references in parentheses applying to this document):

A device (*suitable*) for urinary catheterization comprising a catheter element (18) to be inserted in the urethra of a human, wherein said device comprises a pharmaceutically active composition selected from the group consisting of hormones and said catheter element is adapted to deliver at least a part of said pharmaceutically active composition in the lower urinary track system during catheterisation.

The subject-matter of claim 1 therefore differs from this known from D1 in that the pharmaceutically active composition is deposited on the outer surface of the catheter element.

The problem to be solved by the present invention may therefore be regarded as delivering an active composition in the urinary track system in a passive way.

The solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT), because it is already known from D3 and D4 (see search report) that an active composition can be deposited on the external surface of a catheter in order to be delivered in the urinary track system in a passive way.

2.2 Independent claims 21 and 27 are not new in view of D1 (see search report).

2.3 Independent claim 28 is not inventive in view of D5, since the use of a pharmaceutically active composition instead of a lubricant is an obvious choice for the skilled person (see also D1, D2, D3, D4, D6)

3. Dependent claims 2-20,23 and 29 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step. See for example:

D1 (search report) for claims 2,4,5,14-20,23

D2 (search report) for claims 10,11

D3 (search report) for claims 3,6-9

D4 (search report) for claims 12,13,29

4. Although claims 1 and 28 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

Coloplast

Hormone Catheter, PCT/DK2003/000853
Coloplast A/S, 2002039 - WP
11 February 2005

CLAIMS

1. A device for urinary catheterisation comprising a catheter element adapted to be inserted in the urethra of a human, said catheter element comprising on the outer surface, before insertion of the catheter element, a pharmaceutically active composition comprising at least one agent selected from the group consisting of hormones, efferent blocking agents, afferent blocking agents and sympathomimetic agents, such that the pharmaceutically active composition is delivered to the lower urinary tract system during catheterisation.

2. A device according to claim 1, wherein said pharmaceutically active composition comprises a hormone.

3. A device according to claim 1 or 2, said device being provided in a sealed package, wherein a major part of said pharmaceutically active composition is present on an outer surface of the catheter element.

4. A device according to any of the preceding claims, wherein the pharmaceutically active composition is distributed over a section of the catheter element having a length of at least 50% of the total length of the catheter element.

5. A device according to any of the preceding claims, wherein the catheter element is adapted for intermittent catheterisation.

6. A device according to any of the preceding claims, wherein said catheter element is comprised in a female catheter.

7. A device according to any of the preceding claims, wherein said catheter element has a coating covering at least a portion of the outer surface of the catheter element and said coating contains at least a part of said pharmaceutically active composition and is adapted to release said pharmaceutically active composition within the lower urinary tract system.

8. A device according to any of the preceding claims, wherein at least a part of said catheter element has a polymer coating, and at least a portion of said polymer coating is impregnated with at least a part of said pharmaceutically active composition.

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9. A device according to any of the preceding claims, wherein at least a portion of said catheter element has a hydrophilic coating.

10. A device according to claim 9, wherein said hydrophilic coating is impregnated with at least a part of said pharmaceutically active composition.

11. A device according to any of the preceding claims, wherein said catheter element has depressions on the outer surface, which are adapted to hold at least a part of said pharmaceutically active composition.

12. A device according to any of the preceding claims, wherein at least a part of said pharmaceutically active composition is provided in a gel or crème.

13. A device according to any of the preceding claims, wherein said device is comprising a lubricating gel adapted to reduce friction between the catheter element and urethra, and said gel is containing at least a part of said pharmaceutically active composition.

14. A device according to any of the preceding claims, wherein said device is comprising a discrete unit dose containing said pharmaceutically active composition said device is adapted to shed said discrete unit dose in the lower urinary tract system.

15. A device according to any of the preceding claims, wherein said hormone is a female sex hormone or a derivative thereof.

16. A device according to claim 15, wherein said hormone is selected from oestrogen or an oestrogen derivative.

17. A device according to claim 15 or 16, wherein said hormone is oestriol or oestradiol.

18. A device according to any of the preceding claims, wherein said pharmaceutically active composition comprises an efferent blocking agent selected from the group consisting of anti-cholinergical agents, sympathomimetics agents, alfa-adrenergic agonists and nicotinic cholinergic agonists.

19. A device according to claim 19, wherein said efferent agent is oxybutynin or trospiumchlorid.

20. A device according to any of the preceding claims, wherein said pharmaceutically active composition comprises an afferent blocking agent.

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21. Use of a pharmaceutically active composition comprising at least one agent selected from the group consisting of hormones, efferent blocking agents, afferent blocking agents and sympathomimetic agents, for the manufacture of a device for the treatment, alleviation or prophylaxis of incontinence in a human, said device comprising a catheter element adapted to be inserted in the urethra of said human, said catheter element comprising the pharmaceutically active composition, and said catheter element being adapted to deliver said agent in the lower urinary tract system during catheterisation.

22. The use according to claim 21, wherein the human is a female.

23. The use according to any of the claims 21-22, wherein the device is as defined in any of claims 1-20.

24. A method of treating a human suffering from or being susceptible to incontinence, the method comprising the steps of catheterisation of said human by arranging a proximal end of a catheter element of a device for urinary catheterisation in the urethra of said human, said catheter element comprising a pharmaceutically active composition comprising at least one agent selected from the group consisting of hormones, efferent blocking agents, afferent blocking agents and sympathomimetic agents , and said catheter element being adapted to deliver said composition in the lower urinary tract system during catheterisation.

25. The method according to claim 24, wherein the human is a female.

26. The method according to any of claim 23-24, wherein the device is as defined in any of claim 1-20.

27. A kit comprising a device for urinary catheterisation and a pharmaceutically active composition comprising at least one agent selected from the group consisting of hormones, efferent blocking agents, afferent blocking agents and sympathomimetic agents , said device comprising a catheter element adapted to be inserted in the urethra of a human.

28. A device for urinary catheterisation, said device comprising a catheter element with a proximal end adapted to be inserted in a urinary canal, c h a r a c t e r i s e d i n t h a t said device is comprising a discrete unit dose, said discrete unit dose comprising a pharmaceutically active composition and said catheter element being adapted to shed said pharmaceutically active composition in the lower urinary tract system during catheterisation.

39. A device according to claim 28, wherein said discrete unit dose is placed at the tip of the catheter.